suggested by the Examiner. For at least this reason, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are respectfully requested.

35 USC 103

The Office Action rejects claims 1-10, 16-19, 26-31 and 38 under 35 U.S.C. § 103(a) as being obvious over Greyer et al. (U.S. 5,386,535). Claims 1-10, 27-31 and 38 are also separately rejected under 35 U.S.C. § 103(a) as being obvious over Greyer et al. in view of Gregory et al. (U.S. Patent No. 5,262,179). These rejections are traversed.

The presently claimed invention appears to have been misunderstood. More specifically, in numbered section 13, the Office Action states that prior art compositions having the same or similar components would have the same physical properties.

However, the presently claimed invention is concerned with providing a composition which can be compressed into a tablet having the desired hardness (ie. Crush strength) properties, yet still have an acceptable, relatively fast disintegration time.

It is known that increasing the compaction pressure of when forming a tablet increases its hardness. However, it also significantly increases the disintegration time of the tablet. Since the tablet ideally should have a relatively high crush strength (hardness) and a relatively fast disintegration time, there is always a delicate balancing act in practice to try to optimize both values.

However, the present inventor has found that sodium carbonate or sodium bicarbonate (hereinafter referred to as "sodium (bi)carbonate"), enhances the compressibility of the tablet composition or other dosage form, see page 3, lines 10-14). Thus, tablets including sodium (bi)carbonate can be tabletted with a greater compaction

pressure. Surprisingly, however, this does not result in a correspondingly high disintegration time. Therefore, when tabletting a composition comprising ibuprofen with a carrier which includes sodium (bi)carbonate, it is possible to attain significantly higher crush strengths, yet still provide an acceptable disintegration time. This is reflected in the claimed composition.

This is unexpected because alkali metal (bi)carbonates are not normally used as compressible materials and there is no teaching in the prior art that these materials can have this effect on the formation of tablets.

Greyer et al. (US 5,380,535) teach a chewable oral composition. It reaches the use of sodium (bi)carbonate simply as a buffering agent. There is no teaching or suggestion that it may be included in the composition to permit the composition to be tabletted with a greater compaction pressure, thus resulting in enhanced crush strength and disintegration properties.

Indeed Greyer et al. teach that the compositions may be compressed or non-compressed and, in the examples, the tabletting forces are insufficient to provide the presently claimed crush strengths. In particular, Examples 4, 6, 7 and 8 disclose a tabletting force of only 2500 psi (1.724 MPa). Example 5 discloses a tabletting force of 10000 psi (6.895 MPa) and Example 9 discloses a tabletting force of 5000 psi (3.448 MPa). Thus, there is no suggestion in Greyer et al. that the inclusion of the sodium (bi)carbonate permits a dosage form to be produced which has a crush strength and a disintegration time in accordance with present claim 1.

In addition, there is no incentive from Greyer et al. for a skilled person to increase the tabletting force to provide the claimed crush strength. In fact, there are two clear disincentives for the skilled person to do this. Firstly, a skilled person would believe from his knowledge of crush strengths and disintegration properties that increasing the tabletting force to obtain the claimed crush strength would result in an unacceptable disintegration time. Secondly, Greyer et al. specifically teach that undue hardness should be avoided (column 7, lines 1 to 5).

Gregory et al. (US 5,262,179) teach the use of an alkali metal (bi)carbonate, preferably sodium (bi)carbonate, as a taste masking agent. Although Gregory et al. mention that the compositions disclosed therein may be formed into a tablet, there is no suggestion that, in addition to the taste masking ability of the sodium (bi)carbonate, the sodium (bi)carbonate can also modify the tabletting behaviour of the composition. Thus, there is no incentive from Gregory et al., or a combination of Gregory et al and Greyer et al., for a skilled person to form a dosage form having the crush strength defined in Claim 1.

Elgar et al. (US 4,844,907) teach the use of conventional compression aids such as cellulose granules, starch compounds and microcrystalline cellulose. There is no suggestion in Elgar et al. that an alkali metal (bi)carbonate may be included as a compression aid. Elgar et al teach the required crush strengths for some of the exemplified compositions disclosed therein, but they are silent as regard the disintegration times of these compositions. Moreover, there is no mention by Elgar et al. of the use of an alkali metal (bi)carbonate. Therefore Elgar et al alone is not sufficient to render the subject matter of claim 1 obvious.

Furthermore, a skilled person would have no incentive to combine the tablet compaction process of Elgar et al. with the teachings of Greyer et al. and/or Gregory et al. This is because Greyer et al. relates to chewable compositions and Gregory et al. relates to water soluble compositions, both of which are either in a non-compressed form or a compressed form with a relatively low crush strength. High crush strengths are to be avoided for the compositions of both Greyer et al and Gregory et al. Applicants also take this opportunity to note that, although the text or the rejection refers to Elgar et al., no specific rejection based on Elgar et al. appears to be made in the Office Action. Clarification is respectfully requested.

Accordingly, the subject matter of present claim 1 would not have been obvious in view of Greyer et al., Gregory et al., Elgar et al. or any combination of these documents.

With respect to the Examiner's request in numbered section 17 for comparative data in support of the above arguments, the Examiner's attention is directed to Figures 1 and 2, which clearly show unexpectedly better disintegration times for higher crush strengths (the crush strength being related to the compaction pressure), achieved for compositions which include an alkali metal (bi)carbonate in the carrier.

For at least these reasons, reconsideration and withdrawal of the rejections of claims 1-10, 16-19, 26-31 and 38 and of claims 1-10, 27-31 and 38 under 35 U.S.C. § 103(a) are respectfully requested.

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is

invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this paper is not being timely filed, the applicants respectfully petition for an appropriate extension of time. Any fees for such an extension together with any additional fees may be charged to Counsel's Deposit Account 01-2300.

Respectfully submitted,

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RKC:tdd

Encls: Marked-Up Copy of Amendments to Claims

MARKED-UP COPY OF AMENDMENT TO CLAIMS

1. (Twice Amended) A solid non-effervescent compressed dosage form suitable for oral administration comprising a homogeneous admixture of a racemic ibuprofen medicament present to an extent of 35% or more by weight of the dosage form and [in homogeneous admixture with] a carrier material comprising

i) a compressible filler component combined with a disintegrating component,

ii) 3-20% solid alkali metal carbonate or bicarbonate by weight of the dosage form;

wherein the dosage form has a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes,

provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.